

## REMARKS

After entry of the amendment above, claims 1-4, 7-13, 16-20, 23-26, and 29-37 will be pending as claims 5, 14, 21, 27, and 28 have been canceled. Additionally, new claims 35-37 have been added. Claims 1, 10, 11, 13, 16, and 17 have been amended. These amendments add no new matter and are fully supported by the specification as originally filed. It should be noted that these amendments are not being made for reasons of patentability, but instead reflect Applicants' desire to further prosecution using preferred terminology and to clearly and distinctly pursue claims directed to certain commercially significant embodiments of their invention. Applicants reserve the right to pursue subject matter no longer or not yet claimed in this or a related application.

Turning to the amended and new claims, amended independent claims 1 and 17 are now directed to embodiments wherein the electroporation apparatus has an infusion opening disposed between the first electrode and the second electrode, both of which are proximal to the balloon portion. New claim 10 is directed to embodiments wherein the first and second electrodes of the apparatus are both in between the two balloon portions. Support for these claims is found at specification paragraph 0042 and Figure 1. New independent claim 36 is directed to embodiments of the invention wherein the electroporation apparatus is a guidewire with the second electrode disposed thereon. Support for this claim is found at specification paragraph 0039 and Figure 7. New independent claim 37 is directed to embodiments wherein the second electrode comprises a patch electrode or the like that is not attached to the catheter. Support for this claim is found at specification paragraph 0039 and Figure 6.

Applicants respectfully request reconsideration of the now pending claims in view of the following comments.

Art Rejections

Applicants respectfully traverse the rejection of claims 1-5, 7-14, 16-21, 23-28, and 29-34 under 35 U.S.C. § 102(b) as allegedly anticipated by, or, in the alternative, as supposedly being obvious under 35 U.S.C. § 103(a) over Leone, et al. (U.S. Pat. No. 5,505,700).

Regarding the alleged lack of novelty, a *prima facie* rejection of a claim for anticipation requires both that the cited reference provide an enabling disclosure and describe, either explicitly or inherently, all of the elements of the rejected claim(s). The '700 patent fails to anticipate any of the pending claims, especially as now amended, because they all are directed to an electroporation apparatus wherein the first and second electrodes are configured in such a way to allow an electric field to be generated when a voltage is applied between the first and second electrodes, wherein the electric field is sufficient in strength to electroporate cells in the vessel.

The apparatus disclosed in the '700 patent is not an electroporation apparatus, it is a catheter that provides for iontophoresis, which requires nothing more than a voltage drop between two spaced electrodes. Nowhere does the cited patent teach a device or system useful for electroporation. To the extent the '700 patent mentions electroporation, it does so only in the context of releasing components from cells by breaking those cells down (see column 7, lines 40 – 44), not for introducing components into cells. In contrast, as defined by Applicants, and as generally understood in the art, electroporation is a process for introducing molecules into cells. In general it involves supplying a suitable voltage (according to the formula  $E=V/d$ , where E=electric field strength in V/cm; V=voltage in volts; and d=distance) to a set of electrodes.

In essence, the electric field generated in electroporation creates transient pores in cells without permanently damaging them, allowing a desired therapeutic agent to be taken up and retained by the cells that have been electroporated. See, e.g., specification paragraphs 0022-25. For these reasons it is clear that the '700 patent fails to provide an enabling disclosure with respect to electroporation as it is understood in the art. Furthermore, Applicants note that given the '700 patent's definition of electroporation as a process for breaking cells down to release intracellular components, those in the art would have no reason or motivation to combine the cited patent's contrary teachings with art-understood electroporation methods.

Notwithstanding the blatant deficiencies of the '700 patent with regard to enablement and to advance prosecution Applicants' have amended independent claims 1, 10, and 17 and have added new claims 36 and 37. All of these claims include elements that are neither disclosed nor suggested in the '700 patent. Accordingly, the '700 patent cannot fairly be said to anticipate any of the pending claims. As such, Applicants respectfully request that this rejection be withdrawn.

With respect to the '700 patent allegedly rendering claims 29-34 obvious, Applicants also respectfully traverse. In order to establish a *prima facie* case of obviousness, the burden is on the PTO to provide a convincing line of reasoning as to why the ordinarily skilled artisan would have modified the reference as suggested in the Office action, a reasonable expectation of success, and the presence, explicitly or by suggestion, of all of the elements of the rejected claim(s). See MPEP 2142, *et seq.*

Critically, the motivation must be found in the cited art, and can not be provided merely by conclusory statements set forth in an Office action. See e.g., *In re Lee*, 277 F.3d 1338, 61 USPQ2d 1430 (Fed. Cir. 2002). As discussed above, the '700 patent actually teaches away from the instant invention and in no way suggests, let alone teaches, any of the parameters necessary for applying a suitable voltage to a cell so as to electroporate it without damage for the purpose of introducing molecules, as specifically set forth in claims 29 - 34. The most recent Office action admits as much on page 4. Such parameters are not trivial additions. The appropriate electrode configuration (e.g., distance, electroporating voltage and appropriate field strength) ensures that an electric field of a desired strength is indeed delivered, which is particularly important in the context of electroporation where small changes in electrode distance can have vast effects on electric field strength and cell viability.

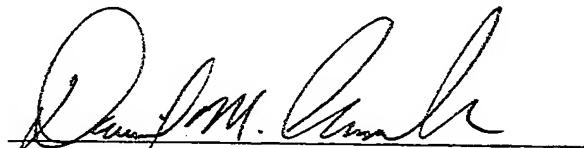
The '700 patent fails to acknowledge this concern and in fact teaches that "electroporation" causes the breakdown of the cell(s) in order to release intracellular components. Hence, this clearly demonstrates that the '700 patent fails to provide the requisite motivation or enabling disclosure to make Applicants' claimed invention. Accordingly, the '700 patent can not render the claimed invention obvious. Thus, this rejection should also be withdrawn.

CONCLUSION

Applicants respectfully submit that all claims are in condition for allowance, and earnestly solicit an early notice to such affect. Should any issues or questions remain, the Examiner is encouraged to telephone the undersigned at 858.735.7090 so that they may be promptly resolved.

Respectfully submitted,

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